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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,798	11/16/1998	SAPE CORNELIS DE VRIES	S-137-1103/S	9123

22847 7590 12/03/2002

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EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/03/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/180,798	DE VRIES ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002 & 16 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

1. The transmittal filed on 16 April 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/180,798 is acceptable and a RCE has been established. An action on the RCE follows.

2. The objection to the abstract is withdrawn in light of the substitute abstract.

3. The rejection of claims 74-78 under 35 U.S.C. 101 is withdrawn, in light of their cancellation.

4. The rejections of claims 59, 60, and 77-81 under 35 U.S.C. 112, 2nd paragraph are withdrawn in light of their cancellation.

5. The rejection of claims 47-82 under 35 U.S.C 112, 1st paragraph, under item 21 of the Office action mailed 01 August 2000 is withdrawn and replaced with the enablement rejection below.

Specification

6. The first line of the last paragraph of page 35 contains the recitation "(Seq ID No. NEW)". The appropriate sequence identifier should replace the term "NEW." New matter must be avoided.

Claim Objections

7. Claims 94 and 95 are objected to because of the following informalities: "Plant" in line 1 of the claims should be replaced with --The plant--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 84-97 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 84: the recitation, "a protein having an amino acid sequence which is at least 90% similar thereto and which hybridizes", in lines 2-3 renders the claims indefinite. The recitation suggests that the protein hybridizes to DNA.

Further in claim 84: the recitation "said isolated DNA having the sequence depicted in SEQ ID No. 2, SEQ ID No. 2, SEQ ID No. 20, or SEQ ID No. 32" renders the claims indefinite. There is insufficient antecedent basis for this limitation in the claim.

Further in claim 84: the recitation "protein kinase having the same activity" in line 6 renders the claim indefinite. It is not clear if the recitation "same activity" is referring to the activity of the protein kinase or to a different activity, and what that activity is.

In claim 87: the claim is indefinite because it broadens the scope of parent claim 84. The isolated DNA of claim 84 must encode a protein that has at least 90% similarity to SEQ ID NOs: 3, 21, or 33. The DNA encompassed by claim 87, however, can encode a protein that is 90% similar to the protein encoded by the DNA of claim 84, and therefore encompasses DNAs that encode proteins that have less than 90% similarity to SEQ ID NOs: 3, 21, or 33.

Further in claim 87: the recitation "the plant into which the DNA is to be inserted" in lines 2-3 renders the claim indefinite. Neither claim 87 nor claim 84 have a prior recitation indicating that the isolated DNA is to be inserted into and expressed in a plant. The recitation "known mRNA stability motifs" also renders the claim indefinite. It is not clear what is meant this recitation, as unknown mRNA stability motifs clearly are not defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 84-97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention, for the reasons of record stated in the Office action mailed 19 June 2001 under item 9 for clams 47-82.

The claims are broadly drawn towards any isolated DNA comprising any sequence encoding any protein kinase having the amino acid sequence depicted in SEQ ID NOs: 3, 21, or 33, or a protein having an amino acid sequence which is at least 90% similar thereto, and which hybridizes under wash conditions of 3x20 min. in 0.5% SSC, 1% SDS at 65°C with the DNA sequence depicted in SEQ ID NOs: 1, 2, 20, or 32, and encoding a protein kinase having the same activity as SEQ ID NOs: 3, 21, or 33; or wherein the DNA sequence is modified in that known mRNA instability motifs or polyadenylation signals are removed or codons preferred by the plant into which the DNA is to be inserted are used, such that the encoded protein is at least 90% similar to the sequence encoded by the unmodified DNA; any expression vector containing the DNA; any plant cell or plant transformed with said vector.

The specification describes the isolation and sequence of the genomic (SEQ ID NO: 1) and cDNA (SEQ ID NO: 2) clones encoding the Daucus carota somatic embryogenesis protein kinase (SERK; SEQ ID NO: 3; page 15, 18-20). The specification indicates that this SERK protein has a leucine-rich repeat, a membrane-spanning region, a region rich in prolines, 11 subdomains characteristic of the catalytic core of protein kinases which suggest a function as a serine/threonine kinase (paragraph bridging pages 19-20). The specification indicates that expression of SEQ ID NO: 1 is closely correlated the occurrence of competent cells in established embryogenic cultures and transiently in zygotic embryogenesis (pages 20-23). The specification also indicates that a HindIII/DraI fragment from SEQ ID NO: 1 containing transcription regulatory sequences was linked to the luciferase coding sequence and introduced

into carrot cells via Agrobacterium. The specification also indicates that an Arabidopsis SERK gene, termed AtSERK, was isolated (SEQ ID NO: 20), and a full-length cDNA clone (SEQ ID NO: 32), encoding SEQ ID NO: 33 (pages 15 and 34).

However, it is not clear that SEQ ID NO: 20 is a full length gene, and that SEQ ID NO: 21 is a full length protein. Page 34, lines 18-31, of the specification indicate that SEQ ID NO: 20 was derived from three different clones of a genomic library of Arabidopsis. Lines 22-23 indicate that fragments spanning the entire coding sequence of the AtSERK gene "are" isolated. The cDNA of AtSERK was also isolated, set forth in SEQ ID NO: 32, the encoded amino acid sequence of which is set forth in SEQ ID NO: 33. However, lines 24 and 25 of page 15 indicate that SEQ ID NO: 20 is a partial genomic clone. Further, if the AtSERK cDNA of SEQ ID NO: 32 corresponds to its genomic clone, they both should encode the same amino acid sequence. However, SEQ ID NO: 21 is clearly different from SEQ ID NO: 33. It is therefore not clear that SEQ ID NO: 20 is a DNA sequence that encodes a full length SERK protein, or that they encode the same amino acid sequence.

In the paper submitted 03 December 2001, Applicants acknowledge that SEQ ID NO: 21 is truncated, but submit that it contains all the highly conserved domains necessary for kinase activity. Applicants argue that subdomain X, which is not present in SEQ ID NO: 21, is not highly conserved among kinases, while subdomain XI, also not present, appears to have some effect on protein stability. While Applicants admit that subdomain XI may provide a stability function, they argue that its absence does not necessarily negate the kinase activity of SEQ ID NO: 21 (paragraph bridging pages 3-4).

Applicants' arguments have been fully considered but were not found persuasive. It is apparent that SEQ ID NO: 21 does not comprise sequences that are required for stabilization. Applicants have not shown that the absence of this domain would not affect its kinase activity, or its activity in the present invention. Applicants have not correlated the function of SEQ ID NOs: 3 or 33 with the structure of SEQ ID NOs: 20 or 21. Applicants further argue that because subdomain X is not highly conserved it is unlikely to serve as an essential domain (paragraph bridging pages 3-4). However, this is only speculation and no supporting data has been described.

Further, claim 84 indicates that the claimed DNAs encode a protein kinase having the same activity as SEQ ID NOs: 3, 21, or 33. However, if "same activity" is referring to the protein kinase, then this recitation does not recite a distinguishing function. That is, numerous kinases are known, but that are distinguished by their biological functions or roles. As currently written, the claims encompass DNA sequences that encode proteins that have the same protein kinase activity as SEQ ID NOs: 3, 21, or 33, but which may have any biological function. Not all such protein kinases may have the same biological function as those of the invention. Further, it is not clear what the activity of SEQ ID NO: 21 is, for the reasons discussed above.

Furtherstill, the specification does not describe all of the promoters listed in claims 90 and 91. The specification on page 35 refers to prior art that teaches the Arabidopsis LTP1 and DMC1 promoters and the petunia FBP7 promoter. However, the only SERK promoter described by the specification is the HindIII/DraI fragment from SEQ ID NO: 1. The sequences from other SERK genes that regulate transcription are not described. The specification also provides no description of the DcEP3-1, AtChitIV, Arabidopsis bel-1, ANT, O126, or pTA7001 promoters.

See Fiers 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing any SEQ ID NOs: 20 and 21, isolated DNAs that encode protein kinases that have any biological function, and the promoters of all SERK genes and other promoters enumerated in the claims, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

10. Claims 84-97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards any isolated DNA comprising any sequence encoding any protein kinase having the amino acid sequence depicted in SEQ ID NOs: 3, 21, or 33, or a protein having an amino acid sequence which is at least 90% similar thereto, and which hybridizes under wash conditions of 3x20 min. in 0.5% SSC, 1% SDS at 65°C with the DNA sequence depicted in SEQ ID NOs: 1, 2, 20, or 32, and encoding a protein kinase having the same activity as SEQ ID NOs: 3, 21, or 33; or wherein the DNA sequence is modified in that known mRNA instability motifs or polyadenylation signals are removed or codons preferred by the plant into which the DNA is to be inserted are used, such that the encoded protein is at least

90% similar to the sequence encoded by the unmodified DNA; any expression vector containing the DNA; any plant cell or plant transformed with said vector.

As discussed above, the specification teaches the isolation and sequence of the genomic (SEQ ID NO: 1) and cDNA (SEQ ID NO: 2) clones encoding the Daucus carota somatic embryogenesis protein kinase (SERK; SEQ ID NO: 3; page 15, 18-20). The specification teaches that this SERK protein has a leucine-rich repeat, a membrane-spanning region, a region rich in prolines, 11 subdomains characteristic of the catalytic core of protein kinases which suggest a function as a serine/threonine kinase (paragraph bridging pages 19-20). The specification teaches that expression of SEQ ID NO: 1 is closely correlated the occurrence of competent cells in established embryogenic cultures and transiently in zygotic embryogenesis (pages 20-23). The specification also indicates that a HindIII/DraI fragment from SEQ ID NO: 1 containing transcription regulatory sequences was linked to the luciferase coding sequence and introduced into carrot cells via Agrobacterium. The specification also teaches that an Arabidopsis SERK gene, termed AtSERK, was isolated (SEQ ID NO: 20), and a full-length cDNA clone (SEQ ID NO: 32), encoding SEQ ID NO: 33 (pages 15 and 34).

However, the specification does not teach that SEQ ID NO: 20 is a full-length gene and that SEQ ID NO: 21 is a full-length protein. As discussed above, Applicants acknowledge that SEQ ID NO: 21 is not a full-length protein, and is missing two subdomains, one of which is required for protein stabilization. It is not clear, and is not taught by the specification, how one skilled in the art can use an unstable protein to make the claimed plant cells and plants and use them in the manner taught by the specification. The specification does not provide any teaching at all indicating how an incomplete SERK can be used with the disclosed invention.

Further, the specification does not teach any mRNA instability motifs of the claimed DNA sequences. In the absence further guidance, undue experimentation would be required by one skilled in the art to locate the any such mRNA instability motifs and remove them. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furtherstill, the specification does not teach all of the promoters mentioned in claims 90 and 91. While the specification at page 35 refers to prior art that teaches the Arabidopsis LTP1 and DMC1 promoters and the petunia FBP7 promoter, the only SERK promoter described by the specification is the HindIII/DraI fragment from SEQ ID NO: 1. The sequences from other SERK genes that regulate transcription are not described. The specification also provides no teaching of the DcEP3-1, AtChitIV, Arabidopsis bel-1, ANT, O126, or pTA7001 promoters, nor is there any indication that they were known in the prior art. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). If the sequence of a gene is not taught, then its promoter is not taught, either. Given the breadth of the claims encompassing SEQ ID NOs: 20 and 21, mRNA instability motifs, and the promoters enumerated in claims 90 and 91, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

11. Claims 84-97 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ashwin D. Mehta, Ph.D.
Patent Examiner

December 2, 2002